

From: Messina, Edward [Messina.Edward@epa.gov]
Sent: 2/8/2019 3:39:25 PM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]
CC: Miller, Wynne [Miller.Wynne@epa.gov]
Subject: RE: Letter on renewing Letter of Intent re: work with China

Some bullets from our prior briefing if you want more. I added to our draft agenda for next week if we want to continue discussions with OCSPP-IO

Background

- The Good Laboratory Practice (GLP) program is a quality management system “intended to assure the quality and integrity of data submitted pursuant to sections 3, 4, 5, 8, 18, and 24(c) of FIFRA” (40 CFR Part 160.1, Scope and Applicability) and “to ensure the quality and integrity of data submitted pursuant to testing consent agreements and test rules issued under section 4 of the Toxic Substances Control Act (TSCA)” (40 CFR Part 792.1).
- In short, GLP assures the data submitted to the Agency, in support of registration applications, are of known and acceptable quality.
 - GLP requirements cover handling of test substances; equipment maintenance and calibration; testing operations; study protocols; quality assurance; recordkeeping and reporting requirements; and testing facility management.
 - Inspection of laboratories that submitted data under GLP requirements is a key component of ensuring data quality and integrity.
 - GLP inspectors document GLP violations in their inspection reports, which are then reviewed by the GLP program manager. The reports with violations are referred to OCSPP, OCE or OCEFT, depending on the nature of the violation, and in accordance with EPA guidance. When OPP receives a referral, we determine the impact to the study, risk assessment, and the registration.
- The U.S. participates in OECD’s Mutual Acceptance of Data (MAD) program, designed to garner international recognition of testing data in support of pesticide and chemical registrations. Currently, 31 member countries and 5 non-member countries participate in evaluating each other’s testing programs.
 - This means the U.S. will accept study data generated in these countries and evaluate them as if they were generated in the US, and *vice versa*.
 - This also allows the Agency to request that our GLP counterparts conduct inspections in those countries should we have any questions or issues with the studies.
 - PRIA 4, should it be enacted, would set aside \$500,000 for GLP enhancements. This would allow the GLP program to hire additional inspectors.

The Current Scope of the Program

- There are approximately 1.5K active public and private U.S. laboratories that submit approximately 9.5K studies to OPP in support of applications for registrations under FIFRA or TSCA.
- From 2013-2017, OECA has averaged approximately 80 on-site inspections per year with approximately 160 studies audited each year.
- OECA has three inspectors and one manager dedicated to the GLP program. The GLP program’s annual budget includes \$50K in extramural resources to support a data system and approximately \$75K in travel.
- In addition to inspections, the GLP program cooperates with and provides technical assistance to the regulated industry and other countries in establishing and harmonizing GLP programs.

Ed Messina
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From: Keigwin, Richard
Sent: Friday, February 08, 2019 10:36 AM
To: Dunn, Alexandra <dunn.alexandra@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Baptist, Erik <baptist.erik@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Subject: RE: Letter on renewing Letter of Intent re: work with China

Alex—

Thanks for your note. This is related to the issue that Jeff raised during one of the IO Huddles earlier this week (in reference to an email that Jeff had received from CropLife America regarding GLP in the context of the work occurring within the OECD). While the OCSPP role in the GLP program is limited, we have been following the issue because of the importance of the GLP program to our decision-making process.

--Rick

From: Dunn, Alexandra
Sent: Friday, February 08, 2019 10:29 AM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Baptist, Erik <baptist.erik@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Subject: RE: Letter on renewing Letter of Intent re: work with China

Let me know what our role is here.

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From: Keigwin, Richard
Sent: Friday, February 8, 2019 9:34 AM
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Cc: Messina, Edward <Messina.Edward@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Subject: FW: Letter on renewing Letter of Intent re: work with China

FYI

From: Bertsch, Charles - FAS <Charles.Bertsch@fas.usda.gov>
Sent: Thursday, February 07, 2019 9:13 AM
To: Bodine, Susan <bodine.susan@epa.gov>
Cc: LaPointe, Loren - FAS <Loren.LaPointe@fas.usda.gov>; Mark.Rasmussen@fas.usda.gov; Caldera, Mayra - FAS <Mayra.Caldera@fas.usda.gov>; Stephens, Andrew - FAS <Andrew.Stephens@fas.usda.gov>; Bomer Lauritsen, Sharon E.

Ex. 6 PP – EOP

Schneller, Keith D.

Ex. 6 PP – EOP

Keigwin, Richard <Keigwin.Richard@epa.gov>

Subject: Letter on renewing Letter of Intent re: work with China

Ms. Bodine –

Please see attached letter from the Undersecretary of Trade and Foreign Agricultural Affairs, Ted McKinney. I am also sending a hard copy of the letter to your office. I greatly appreciate your attention to this matter.

Thanks and regards – Chuck Bertsch

Charles R. Bertsch
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